11-1-06

Attorney's Docket No.: 17111-007US1 / 2307US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: James G. Keck et al.	Art Unit	: 1633
Serial No.	: 09/601,997	Examiner	: Epps-Ford , Janet L.
Filed	: December 15, 2000	Conf. No.	: 5984
Cust. No.	: 20985		
Title	: NON-BACTERIAL CLONING IN DELIVERY AND EXPRESSION OF NUCLEIC ACIDS		

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith is a Petition pursuant to 37 C.F.R. §1.181 with a check for the requisite fee ($130.00) for filing in connection with the above-identified application.

☒ The Commissioner is hereby authorized to charge the fee for the extension of time and any other fee that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie Seidman
Reg. No. 33,779

Attorney Docket No. 17111-007US1/2307US
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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie Seidman

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PETITION PURSUANT TO 37 C.F.R. §1.181

Mail Stop Petition
Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant hereby submits a Petition pursuant to 37 C.F.R. §1.181 for reconsideration and removal of the finality of the Office Action, mailed October 18, 2006, in connection with the above-captioned application. This Petition is filed within two months of the mailing of the final rejection.

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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie Seidman

REMARKS

Enclosed herewith is a check including the fee for this Petition, as prescribed in 37 C.F.R. §1.17(i). If the accompanying fee is incorrect or missing or d additional fees are required, authorization is hereby given to charge Deposit Account No. 06-1050.

It respectfully is submitted that the Office Action mailed October 18, 2006, (hereinafter the instant Office Action), which was made Final, introduces new grounds of rejection of claims 58, 59, 60-63 and 70 under 35 U.S.C. §112, second paragraph, that were not necessitated by amendment. Several grounds of rejection (i) could have been applied in one of several previous Office Actions, including the first Office Action and the most recent previous Office Action, mailed October 20, 2005 (hereinafter the previous Office Action), which was a final Office Action whose finality was withdrawn; and (ii) were not necessitated by the claim amendments in response to the previous Office Action. Therefore, the instant Action should not have been made Final. Exemplary new grounds of rejection under 35 U.S.C. §112, second paragraph, set forth in the instant Office Action are as follows:

I. NEW GROUND OF REJECTION OF CLAIM 58

In the instant Office Action, Claim 58 is rejected as vague and indefinite because the recitation "antisense strand that, when expressed as RNA, binds to an mRNA transcribed from the target nucleic acid sequence" (lines 15-16) allegedly suggests that the antisense RNA produced from the sense strand targets an mRNA other than the mRNA "coded for by a sample nucleic acid in the target nucleic acid" as set forth in the preamble of the method. The Examiner further alleges that the claim as a whole is incomplete because there is no mention of a control, untransfected host cell for comparison with the transfected cell when analyzing changes in phenotype in the transfected cell.

Applicant respectfully submits that the above grounds of rejection of Claim 58 could have been applied in the previous Office Action mailed October 20, 2005, whose finality is withdrawn herein, or indeed in any one of several non-final earlier Office Actions that issued in connection with the above-captioned application including, for example, the Office Action mailed January 9, 2003, the Office Action mailed April 20, 2004, and the Office Action mailed February 3, 2005. As discussed below, the claims have never mentioned a control, and have never been rejected on this basis.

Hence neither of the above rejections were necessitated by Applicant's amendments responsive to the previous Office Action nor any Office Action.

(A) Claim 58 as pending at the time the previous Office Action was mailed (October 20, 2005)

For example, at the time that the previous Office Action, whose finality is withdrawn in the instant final Office Action, was mailed (October 20, 2005), Claim 58 was amended to incorporated limitations of a base claim. It recited:

> A high-throughput method of assigning a function associated with a product coded for by a sample nucleic acid sequence in a target nucleic acid molecule, said method comprising:
>
> a) without any intervening bacterial cloning steps and without any conformational modeling of mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence, delivering into and amplifying and expressing a plurality of members of an oligonucleotide family as individual transcription products in a plurality of recombinant non-bacterial host cells comprising the target nucleic acid molecule that comprises the sample nucleic acid sequence, whereby the method is high-throughput, wherein:
>
> the members of the oligonucleotide family comprise a plurality of nucleic acids each encoding a transcription product comprising a sequence that is complementary to a sequence contained in the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence;
>
> the plurality of members of the oligonucleotide family are introduced into expression vectors, which are introduced into the host cells, wherein the expression vectors comprise:
>
> double-stranded DNA, comprising:
>
> a sense strand and an antisense strand, wherein the sense strand codes for an **antisense strand that, when expressed as RNA, binds to an mRNA sequence transcribed from the target nucleic acid sequence** so that expression of a product from the target nucleic acid is inhibited; and
>
> means for determining directionality of expression, wherein the product is associated with at least one phenotypic property of a host cell containing the mRNA sequence; and wherein the expression vector is for expression in non-bacterial host cells;
>
> the coding sequences for each individual transcription product encodes an antisense nucleic acid that, when expressed as RNA, binds to the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence; and

expression of one or more of the individual transcription products inhibits production of a product of the mRNA; and

b) **in the resulting host cells, analyzing changes in phenotype** to thereby assign a function associated with the product encoded by the sample nucleic acid sequence in the target nucleic acid molecule. (emphasis added).

(B) Claim 58 as presently pending

Claim 58 as presently pending recites:

A high-throughput method of assigning a function associated with a product coded for by a sample nucleic acid sequence in a target nucleic acid molecule, said method comprising:

a) without any intervening bacterial cloning steps and without any conformational modeling of mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence, delivering into and amplifying and expressing a plurality of members of an oligonucleotide family as individual transcription products in a plurality of recombinant non-bacterial host cells comprising the target nucleic acid molecule that comprises the sample nucleic acid sequence, whereby the method is high-throughput, wherein:

the plurality of members of the oligonucleotide family are introduced into expression vectors, which are introduced into the host cells, wherein the expression vectors comprise:

double-stranded DNA, comprising:

a sense strand and an antisense strand, wherein the sense strand codes for an **antisense strand that, when expressed as RNA, binds to an mRNA sequence** transcribed from the target nucleic acid sequence so that expression of a product from the target nucleic acid is inhibited; and

means for determining directionality of expression, wherein the product is associated with at least one phenotypic property of a host cell containing the mRNA sequence; and wherein the expression vector is for expression in non-bacterial host cells;

the coding sequence for each individual transcription product encodes an antisense nucleic acid that binds to the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence; and

expression of one or more of the individual transcription products inhibits production of a product of the mRNA; and

b) **in the resulting host cells, analyzing changes in phenotype** to thereby assign a function associated with the product encoded by the sample nucleic acid sequence in the target nucleic acid molecule. (emphasis added)

As the emphasized (bold) sections of Claim 58 as recited in (A) and (B) above show, the bases for rejection of Claim 58 ("antisense RNA," lines 15-16; the step of analyzing changes in phenotype not including a comparison to an untransfected control cell), have not been amended responsive to the previous Office Action. Therefore, to the extent Claim 58 can be rejected as indefinite due to alleged lack of clarity of "antisense RNA" or for failing to recite a control, these new rejections could have been applied in a previous Office Action.

II. NEW GROUNDS OF REJECTION OF CLAIM 59 (AND DEPENDENT CLAIMS 60-63 AND 70)

Similarly, in the instant Office Action, the Examiner rejects Claim 59 (and dependent claims 60-63 and 70) as unclear in the recitation of "a catalytic domain that cleaves **an** mRNA sequence transcribed from the target nucleic acid" because the recited phrase allegedly suggests **multiple** mRNA sequences transcribed from the target nucleic acid, whereas the goal of the method is to assign a function to a product coded for by **a sample nucleic acid sequence** in a target nucleic acid. Claim 59 is further rejected as indefinite because the phrase "the RNA" in line 1 allegedly does not clearly identify to which RNA it refers.

Applicant respectfully submits that the above grounds of rejection of Claim 59 and claims dependent thereon could have been applied in the previous Office Action, mailed October 20, 2005, or in any one of several earlier Actions as discussed above for Claim 58. Neither of the rejections of Claim 59 and its dependents were necessitated by Applicant's amendments responsive to the previous Office Action. Therefore, this new ground of rejection was not necessitated by amendment.

(A) Claim 59 as pending at the time the previous Office Action was mailed (October 20, 2005)

For example, at the time that the previous final Office Action, whose finality is withdrawn in the instant final Office Action, was mailed (October 20, 2005), Claim 59, incorporating the limitations of the base claim 58, recited:

> A high-throughput method of assigning a function associated with a product coded for by a sample nucleic acid sequence in a target nucleic acid molecule, said method comprising:
>
> a) without any intervening bacterial cloning steps and without any conformational modeling of mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence, delivering into and

amplifying and expressing a plurality of members of an oligonucleotide family as individual transcription products in a plurality of recombinant non-bacterial host cells comprising the target nucleic acid molecule that comprises the sample nucleic acid sequence, whereby the method is high-throughput, wherein:

the members of the oligonucleotide family comprise a plurality of nucleic acids each encoding a transcription product comprising a sequence that is complementary to a sequence contained in the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence;

the plurality of members of the oligonucleotide family are introduced into expression vectors, which are introduced into the host cells, wherein the expression vectors comprise:

double-stranded DNA, comprising:

a sense strand and an antisense strand, wherein the sense strand codes for an antisense strand that, when expressed as RNA, binds to an mRNA sequence transcribed from the target nucleic acid sequence so that expression of a product from the target nucleic acid is inhibited; and

means for determining directionality of expression, wherein the product is associated with at least one phenotypic property of a host cell containing the mRNA sequence; and wherein the expression vector is for expression in non-bacterial host cells;

the coding sequences for each individual transcription product encodes an antisense nucleic acid that, when expressed as RNA, binds to the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence; and

expression of one or more of the individual transcription products inhibits production of a product of the mRNA; and

b) in the resulting host cells, analyzing changes in phenotype to thereby assign a function associated with the product encoded by the sample nucleic acid sequence in the target nucleic acid molecule, wherein **the RNA** comprises:

a catalytic domain that cleaves an mRNA sequence transcribed from the target nucleic acid; and

binding sequences flanking the catalytic domain for binding the RNA to the mRNA, and/or wherein the means for determining directionality of expression comprises a different non blunt-ended restriction enzyme site at each end of said double-stranded DNA. (emphasis added)

(B) Claim 59 as presently pending

Claim 59 as presently pending, incorporating the limitations of base Claim 58, recites:

A high-throughput method of assigning a function associated with a product coded for by a sample nucleic acid sequence in a target nucleic acid molecule, said method comprising:

a) without any intervening bacterial cloning steps and without any conformational modeling of mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence, delivering into and amplifying and expressing a plurality of members of an oligonucleotide family as individual transcription products in a plurality of recombinant non-bacterial host cells comprising the target nucleic acid molecule that comprises the sample nucleic acid sequence, whereby the method is high-throughput, wherein:

the plurality of members of the oligonucleotide family are introduced into expression vectors, which are introduced into the host cells, wherein the expression vectors comprise:

double-stranded DNA, comprising:

a sense strand and an antisense strand, wherein the sense strand codes for an antisense strand that, when expressed as RNA, binds to an mRNA sequence transcribed from the target nucleic acid sequence so that expression of a product from the target nucleic acid is inhibited; and

means for determining directionality of expression, wherein the product is associated with at least one phenotypic property of a host cell containing the mRNA sequence; and wherein the expression vector is for expression in non-bacterial host cells;

the coding sequence for each individual transcription product encodes an antisense nucleic acid that binds to the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence; and

expression of one or more of the individual transcription products inhibits production of a product of the mRNA; and

b) in the resulting host cells, analyzing changes in phenotype to thereby assign a function associated with the product encoded by the sample nucleic acid sequence in the target nucleic acid molecule, wherein **the RNA** comprises:

a catalytic domain that cleaves an mRNA sequence transcribed from the target nucleic acid; and

binding sequences flanking the catalytic domain for binding the RNA to the mRNA, and/or wherein the means for determining directionality of expression

comprises a different non blunt-ended restriction enzyme site at each end of said double-stranded DNA. (emphasis added)

Thus, the limitations in claim Claim 59 and claims dependent thereon upon which the claims are rejected (*see* emphases in bold - alleged lack of clarity of "the RNA;" alleged lack of clarity of the phrase "a catalytic domain that cleaves an mRNA sequence"), were not amended responsive to the previous Office Action. Therefore, to the extent Claim 59 can be rejected as indefinite due to alleged lack of clarity of "the RNA" or " a catalytic domain that cleaves an mRNA sequence," these new rejections could have been applied in the previous Office Action. Therefore, this new ground of rejection was not necessitated by amendment.

Failure to withdraw the finality of the instant Office Action denies the Applicant the right to amend the claims, if needed, and/or provide arguments to overcome these rejections, not previously of record during the prosecution of this application. Therefore, because the newly recited rejection of Claims 58 and 59 and claims dependent thereon under 35 U.S.C. §112, second paragraph, as to indefiniteness were not necessitated by amendment and could have been raised in the previous Office Action, the finality of the instant Office Action is improper.

* * *

In light of the above remarks, reconsideration and removal of the finality of the instant Office Action are respectfully requested.

Respectfully submitted,
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